

## REMARKS

### I. Claim Status.

Claims 1-16, 18-37 and 39-41 are pending in the application. Claims 15, 16, 18, 36, 37, and 39 are withdrawn. This Response and Amendment amends claims 1, 19, and 40 and cancels claims 7 and 24.

### II. Claim Amendments.

Claims 1, 19, and 40 have been amended to recite the limitation “wherein the drug is released from the perforated tablet at a zero-order, or a near zero-order kinetic release rate in the aqueous environment above a pH of about 5.” Support for this amendment is found in the Specification on page 12, lines 8-9. Accordingly this amendment does not add new matter. Entry of the amendments to claims 1 and 19 is respectfully requested.

### III. The Rejection Under 35 USC § 103(a).

Claims 1-14, 19-35, and 40-41 are rejected under 35 USC § 103(a) as being unpatentable over Kim (US 6,110,500) in view of Marvola et al. (US 5,962,024) for the reasons stated in paragraph 9 of the Office Action.

#### A. There Is No Motivation To Modify Or Combine The References To Arrive At Applicant's Invention.

The Applicant respectfully submits that there is no motivation to combine the above-cited references and that a *prima facie* case has not been established. The Applicant requests withdrawal of the rejection and allowance of all claims on this basis.

All of the independent claims, Claims 1, 19, and 40 are limited to a perforated tablet, “wherein the drug is released from the perforated tablet at a zero-order, or near zero-order kinetic release rate, in the aqueous environment above a pH of about 5.” Kim does not teach this limitation. Although Kim teaches near zero order kinetics, Kim also teaches a parabolic release rate. Kim does not teach a zero-order or near zero order release rate in an aqueous environment above a pH of about 5 as claimed by Applicant. Although Marvola discloses a pH-sensitive polymer, there is no teaching that the combination would produce a tablet that would produce a tablet with zero-order kinetics.

Marvola teaches a tablet having a pH sensitive polymer, but the tablets disclosed in

Marvola exhibit first-order kinetics. See, Figure 1. There is no suggestion in Marvola that the combination of the pH sensitive polymer, when formed into a perforated tablet, would exhibit zero-order kinetics. Kim also does not provide this motivation. Kim teaches both zero-order and parabolic kinetic release rates. Kim teaches a parabolic release profile for drug loadings of 10% to 39% by weight, and a zero-order at higher drug loading (e.g., col. 7-8), and non-linear (and non-parabolic) release profile of a water insoluble polymer (e.g., col. 9). There is no teaching that varying the amount of polymer, either in Kim or Marvola, would change the kinetic release rate of the drug.

Contrary to the assertion of the Examiner, one skilled in the art would not be motivated to vary the amount of the enteric polymer in the formulation in order to achieve the linear release rate for the drug, because there is no teaching that changing the amount of enteric polymer leads to a zero-order kinetic rate. Further, as stated in the Specification, page 19, lines 13-16, “[a]s shown by Equation (2) the rate is independent of the thickness of the tablet. Thus, the same kinetic drug release rate in different drug loading formulations can be obtained by adding more drugs while the same composition proportions are maintained.” Accordingly, as the release rate of the table according to the invention is independent of the amount of the composition proportions, and neither Kim nor Marvola alone, nor in combination teach that an enteric polymer would have zero order kinetics, the Examiner has not shown a motivation to combine the references. Withdrawal of the rejection and allowance of all claims is requested on this basis.

### CONCLUSION

The Applicant believes that all pending claims are in condition for allowance and such action is earnestly requested. If the present amendments and remarks do not place the Application in condition for allowance, the Examiner is encouraged to contact the undersigned directly if there are any issues that can be resolved by telephone with the Applicant's representative.

The Commissioner is hereby authorized to charge payment of any fees associated with this communication, if such fees are due, to Deposit Account No. 19-2090.

Respectfully Submitted,

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